K003257

DEC 22 2000

Special 510(k) Summary

CyberCare Technologies, Inc. EHC400 Desktop Patient Station
CyberCare Technologies, Inc. EHC600 Care Provider Station

The following information is in accordance with 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CyberCare Technologies Inc.

7840 Roswell Rd.
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Tel (770) 350-1570
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Contact Person: Gordon J. Peters, Director Regulatory Compliance

Date Prepared: October 12, 2000

Name of Device

CyberCare EHC400 Desktop Patient Station, CyberCare Technologies, Inc. EHC600 Care Provider Station

Device Classification/Classification Panel

Powered Communication System
21 CFR 890.3710 ILQ Class II

Noninvasive Blood Pressure Measuring Systems
21 CFR 870.1130 DXN Class II

Clinical Electronic Thermometer
21 CFR 880.2910 FLL Class II

Noninvasive Pulse Oximeters
21 CFR 870.2700 DQA Class II

Electronic Stethoscope
21 CFR 870.1875 (b), (1) DQD Class II

Glucometer
21 CFR 862.1345 CGA Class II

Cardiovascular Devices Panel/Clinical Chemistry

Predicate Device

CyberCare EHC400 Desktop Patient Station
LifeScan One Touch Profile Diabetes Tracking System a Johnson & Johnson Co.

INTENDED USE

The CyberCare EHC400 Desktop Patient Station (EHC400) is a patient monitoring system intended to provide out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The modified EHC400 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station providing two-way video, audio and data communication between the two stations. The system monitors the following physiologic functions: blood pressure (sphygmomanometer), blood oxygen saturation (pulse oximeter), heart rate (pulse oximeter), temperature (electronic oral thermometer) heart, lung, and bowel sounds (electronic stethoscope) and a Blood Glucose monitor, which provides blood glucose test results to the EHC400 unit.

DESCRIPTION OF THE DEVICE/SUBSTANTIAL EQUIVALENCE

The modified EHC400/600 is a patient monitoring system intended provide out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The modified EHC400 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station providing two-way video, audio and data communication between the two stations. The system monitors the following physiologic functions: blood pressure (sphygmomanometer), blood oxygen saturation (pulse oximeter), heart rate, (pulse oximeter), temperature, (electronic oral thermometer) and heart, lung, and bowel sounds (electronic stethoscope). The modified EHC400/600 consists of a touch screen computer and a vital signs unit equipped with a noninvasive blood pressure (NIBP), oximeter (SpO_2 and heart rate), electronic oral thermometer (temperature), an electronic stethoscope (pending separate approval) and a Blood Glucose monitor, which provides blood glucose test results to the EHC400 unit. The system consists of a Care Provider Station (EHC600) and a Desktop Patient Station (EHC400) with two-way video, audio and data communication between the two. The modified EHC400/600 has already been cleared by FDA for monitoring blood pressure, oxygen saturation, heart rate and temperature (K000237). The only significant modification to the cleared EHC400/600 is the addition of an approved (K950727) Blood Glucose monitor to the modified EHC400.

The modified EHC400/600 with Blood Glucose monitor and its predicate devices have the same intended use and similar indications for use. The modified EHC400/600 is the same device as the cleared EHC400/600 (K000237), except for the addition of the Blood Glucose monitor. The addition of the Blood Glucose monitor does not present any new issues of safety or effectiveness, because the issues in all cases is whether the modified EHC400 accurately transmits the data as supplied to it from the Blood Glucose monitor. Furthermore, the company's design control activities, discussed below, confirm that the modified EHC400/600 continues to perform within its specification with the addition of the Blood Glucose monitor. Thus, the modified EHC400/EHC600 with the Blood Glucose monitor is substantially equivalent to its predicate devices, the previously cleared EHC400/EHC600, and the LifeScan One Touch Profile Diabetes Tracking System.

PERFORMANCE DATA

The EHC400 uses currently available technology found in legally marketed devices. Testing, to ensure that the EHC400 would perform as intended, was conducted at two levels: Non-clinical bench testing to test each function and clinical testing using volunteers to verify performance of the Blood Glucose monitor.

The EHC400 meets applicable standards for performance and EMC compliance.

Non-clinical Testing

Testing was performed to evaluate the functional modules within the predicate EHC400. These tests were repeated on the EHC400 containing the Blood Glucose monitor. The testing shows that the vital signs modules in the EHC400 with the Blood Glucose monitor operates substantially the same as those in the predicate EHC400

Clinical Testing

Clinical testing was performed on 25 subjects under an appropriate IRB approved protocol. All Blood Glucose monitor comparisons were taken with the individual seated adjacent to the Patient Terminal (EHC400) in a normal operating environment. The testing shows that the CyberCare Blood Glucose monitor data was accurately received and forwarded by the EHC400 to the EHC600 care provider's station.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2000

Mr. Gordon J. Peters
Director Regulatory Compliance
CyberCare Technologies, Inc.
7840 Roswell Road, Bldg. 300
Suite 320
Atlanta, Georgia 30350

Re: K003257
Trade Name: EHC400 Desktop Patient Station/EHC600 Care Provider Station
Regulatory Class: II
Product Code: CGA
Dated: October 13, 2000
Received: October 18, 2000

Dear Mr. Peters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K003257

Device Name: CyberCare EHC400 Desktop Patient Station/
EHC600 Care Provider Station

Indications for Use:

The CyberCare EHC400 Desktop Patient Station (EHC400) is a patient monitoring system intended to provide out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC400 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station to provide two-way video, audio and data communication between the two stations. The system monitors the following physiologic functions: blood pressure (sphygmomanometer), blood oxygen saturation (pulse oximeter), heart rate (pulse oximeter), temperature (electronic oral thermometer) heart, lung, and bowel sounds (electronic stethoscope) and blood glucose (Glucometer).

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003257